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EXAMINER	
PARKIN,J	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No.: 38

Application Number: 08/466,921
Filing Date: 06 June, 1995
Appellants: Alizon *et al.*

Salvatore J. Arrigo
For Appellant

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed 21 June, 2000.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims do not stand or fall together and provides reasons as set forth in 37 C.F.R. § 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

No prior art is relied upon by the Examiner in the rejection of claims under appeal.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 68 and 69 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. As previously set forth in Paper No. 29, the reference to "amplified" copies of HIV-1 DNA fragments is vague and indefinite. The disclosure fails to provide an adequate definition of this phrase. This phrase is confusing since the precise nature of the amplification is not clearly set forth. For instance, it is not readily manifest if the claims are directed toward the amplification and plaque purification of a lambda phage clone containing an HIV-1 insert, PCR amplified HIV-1 fragments (which are clearly not supported by the disclosure), or some other form of amplified DNA. Moreover, Appellants have failed to provide any literature at the time of filing providing a suitable definition. Accordingly, the skilled artisan would not be able to ascertain the precise metes and bounds of the claimed invention.

Claims 62-73 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). The claims are directed toward purified HIV-1 DNA fragments, cloned HIV-1 DNA fragments, double-stranded HIV-1 DNA fragments, amplified HIV-1 DNA fragments, and vectors and transformed host cells containing said fragments. Claim limitations stipulate that

fragments hybridize to HIV-1 genomic DNAs under non-stringent hybridization conditions comprising 20% formamide, 8X SSC, at a temperature 37°C, followed by washing conditions of 2X SSC, 0.1% SDS, at a temperature 37°C. As previously noted, although the disclosure describes similar hybridization conditions to those claimed by applicants, these conditions were discussed in reference to hybridization assays performed between three isolated LAV cDNA clones (e.g., λJ19, λJ27, and λJ81) and cloned HTLV-II DNA (see pages 11 and 12 of the disclosure). Thus, the purpose of this hybridization assay was to assess the genetic relatedness of the recently identified LAV cDNA clones to that of other known retroviruses (e.g., HTLV-II). Moreover, the claims encompass an exceedingly large genus of nucleic acids encompassing small fragments from 10-15 nt to full-length proviral genomes (~10 kb). However, the disclosure fails to describe any other nucleic acids with the exception of those specific λJ19, λJ27, and λJ81 restriction fragments provided. The disclosure does not provide restriction maps or nucleotide sequences from any other HIV-1 isolate. The disclosure does not describe hybridization assays involving λJ19 restriction fragments and other HIV-1 clones. Moreover, the disclosure fails to describe the preparation of amplified DNA fragments. Accordingly, the skilled artisan, upon perusal of the specification, would not reach the conclusion that applicants' contemplated isolating and purifying other HIV-1 fragments that hybridize under the precise conditions claimed. Accordingly, applicants have not met their burden pertaining to this aspect of § 112. See also *Bigham* v. *Godtfredsen*, 857 F.2d 1415, 8 U.S.P.Q.2d 1266 (Fed. Cir. 1988), wherein the court concluded that the disclosure of an earlier compound was insufficient to provide an adequate written description for later claimed variants of this compound. Applicants submit that an

adequate written description is provided by the disclosure. These arguments are not deemed persuasive for the reasons note above.

(11) Response to Argument

Appellants' arguments pertaining to the rejection of claims 68 and 69 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, were fully addressed in the grounds for rejection set forth *supra*. It is again noted that the disclosure fails to define this term and that Appellants have failed to provide any publications that provide a clear and concise explanation of the term as it is applied in the art.

Appellants' arguments pertaining to the rejection of claims 62-73 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, will be addressed as follows:

Contrary to Appellants' arguments, the disclosure fails to describe the isolation and purification of HIV-1 DNA fragments that hybridize to HIV-1 genomic DNA under the recited hybridization conditions. The only hybridization conditions provided in the disclosure were provided in reference to hybridization assays performed between three isolated LAV cDNA clones (e.g., λJ19, λJ27, and λJ81) and cloned HTLV-II DNA (see pages 11 and 12 of the disclosure). The purpose of this hybridization assay was to assess the genetic relatedness of the recently identified LAV cDNA clones to that of other known retroviruses (e.g., HTLV-II). Interestingly, the disclosure states (see p. 11, lines 31-34) that under the hybridization conditions Appellants are attempting to

claim that "no hybridization was detected after two days exposure at -70°C using an intensifying screen." Thus, these hybridization conditions were clearly described in reference to a comparative assay to assess the genetic relatedness of the full-length clones to other known human retroviruses. These hybridization conditions were not employed as further defining criteria to identify other suitable HIV-1 fragments that would hybridize with any HIV-1 genomic DNA.

Moreover, Appellants reliance upon pages 10 and 11 of the disclosure for support is also erroneous. The passages relied upon fail to disclose the precise hybridization conditions now being claimed. The passage relied upon demonstrates that λJ19 and λJ81 appear to be closely related to each other as ascertained by Southern blotting. Interestingly, this assay was performed under "stringent hybridization and washing conditions". Stringent hybridization conditions are often associated with high temperatures and low salt in both the hybridization reaction and washing conditions. However, the claimed invention recites low stringency conditions which would not be conducive to the identification of HIV-1-specific probes or fragments.

Appellants further suggest that the Office has failed to set forth a *prima facie* basis for the rejection and fails to explain why the skilled artisan would reach the same conclusion as the Examiner regarding the lack of written description for the claimed compounds. A *prima facie* case was already clearly set forth in the last Office action (see Paper No. 29) and *supra*. Appellants are reminded that the claims encompass an exceedingly large genus of nucleic acids encompassing small fragments from 10-15 nt to full-length proviral genomes (~10 kb). Perusal of the disclosure suggests that Appellants were in possession of what appear to be three full-length proviral clones (e.g., λJ19, λJ27, and λJ81) and

three smaller clones (e.g., pLAV13, pLAV82, and pLAV75) corresponding to the R and U3 regions of the long terminal repeat (LTR). Page 4 of the specification and Figure 2 provide further guidance pertaining to a preliminary restriction map of the full-length clones. Thus, the skilled artisan would reasonably conclude that Appellants were in possession of these DNAs. However, nothing in the disclosure suggests that Appellants contemplated making and using HIV-1 DNA fragments with the recited properties. The disclosure fails to provide a clear description of those criteria to be employed in identifying other suitable HIV-1 fragments. The disclosure describes the construction of a cDNA library (pages 5 and 6), the identification and preliminary restriction analysis of what appear to be HIV-1/LAV-specific cDNA clones (pages 7-11), and a comparative assay involving the identified full-length clones and other known retroviruses (e.g., HTLV-I, -II, Visna) (pages 11-12). However, once again, the disclosure fails to set forth any specific guidance for the identification, isolation, and characterization of purified DNA fragments under the recited hybridization conditions. The disclosure also fails to describe the preparation of amplified DNA fragments. Accordingly, the skilled artisan, upon perusal of the specification, would not reach the conclusion that applicants' contemplated isolating and purifying other HIV-1 fragments that hybridize under the precise conditions claimed. Accordingly, applicants have not met their burden pertaining to this aspect of § 112. See also *Bigham* v. *Godtfredsen*, 857 F.2d 1415, 8 U.S.P.Q.2d 1266 (Fed. Cir. 1988), wherein the court concluded that the disclosure of an earlier compound was insufficient to provide an adequate written description for later claimed variants of this compound.

Appellants assert that they were in possession of what appear to be two-full length proviral molecular clones of LAV (or HIV-1)

designated λ-J19 and λ-J81. The Examiner does not dispute this assertion. Appellants also assert that they were in possession of specific LAV restriction fragments. The Examiner does not dispute this finding either but would like to emphasize that the claimed invention is not limited to any given restriction fragment.

The Examiner does not concur with Appellants' assessment that they were in possession of amplified copies of DNA. Amplified could reasonably be construed by the skilled artisan as referencing PCR-amplified copies of DNA. For instance, a specific segment of the HIV-1 genome could be amplified using an oligonucleotide primer pair. However, no such support exists for amplified DNAs anywhere in the specification. Appellants' reliance on page 12 of the disclosure is inappropriate and insufficient. The passage relied upon refers to cloned probes that can be made from a DNA fragment described in the specification (e.g., LAV 13). However, this section fails to set forth any clear and concise steps for amplifying DNA fragments with the recited characteristics.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Jeffrey S. Parkin, Ph.D.
Patent Examiner

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25 August, 2000